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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,933	10/20/2003	Helmut D. Link	246472006000	8319

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EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,933

Applicant(s)

LINK, HELMUT D.

Examiner

David Comstock

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,7,8 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,7,8 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: It is noted that page 2, lines 6-11, referring to the radius of curvature of the slide surfaces contradicts page 4, lines 21-27, referring to the hinge radius, since the former citation states that the radius of the slide surfaces increases in a cranial direction and the latter citation states that the hinge radius is smaller in a cranial direction. However, since the two dimensions are directly related, both the radius of curvature of the slide surface and the hinge radius should together be either larger or smaller in the cranial direction and not inversely related.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Berry (5,895,428; cited by Applicant).

Berry discloses an implant method and system comprising installing different prostheses 11 having sliding hinges 29,43 (see Figs. 2 and 12-19 and col. 4, lines 11-23). The prostheses have differing extents, radii of curvature, and effective hinge centers, and range in size from small to large (cf. Fig. 12). The appropriate hinge and

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prostheses dimensions, e.g. hinge radius of an affected joint, are determined by tomography and the prostheses are accordingly sized and implanted to accommodate individual anatomy (col. 4, lines 19-23).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berry (5,895,428; cited by Applicant).

Berry discloses the claimed invention except for explicitly disclosing providing slide surface radii of below 15 mm or 18 mm for a prosthesis and over 18 mm for another prosthesis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device with a slide surface radii below 15 mm or 18 mm for one prosthesis and over 18 mm for another prosthesis, or with any of numerous slide surface radii, since it has been held that where the general conditions of a claim are disclosed in the prior art, i.e. sliding joint prostheses of different sizes, discovering the optimum or workable ranges of the same involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 14 December 2004 have been fully considered but they are not persuasive.

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In response to Applicant's argument that Berry does not anticipate or render obvious Applicant's invention, and with respect to claim 8, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Here, claim 8, essentially requires only that one of two prostheses have a greater slide surface radius of curvature than the other and that the former is *capable of being selected* to replace an intervertebral disk lying in a more cranial direction than the other. Berry clearly discloses at least two prostheses wherein one has a greater slide surface radius of curvature than another. Furthermore, if it were so desired, there is nothing to preclude one having a greater radius from being selected to replace an intervertebral disk lying in a more cranial direction. With respect to claim 7, it is noted that Berry does disclose the claimed method, albeit not with the same language as Applicant. It is noted that all of the disclosures in a reference must be evaluated for what they fairly teach one of ordinary skill in the art. Furthermore, the embodiment which anticipates the claimed invention need not be the preferred embodiment. *In re Smith*, 32 CCPA 959, 148 F.2d 351, 65 USPQ 167; *In re Nehrenberg*, 47 CCPA 1159, 280 F.2d 161, 126 USPQ 383; *In re Watanabe*, 50 CCPA 1175, 315 F.2d 924, 137 USPQ 350. Contrary to Applicant's assertion, Berry discloses

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a step of determining a hinge radius of an affected joint, as already set forth in the rejection. Berry states, "the exact size of the implant 11 may be formed based upon a tomographic representation of each individual's vertebrae pair, between which the implant 11 is to be placed." Berry, column 4, lines 20-23. Furthermore, as shown in Figure 12, and as acknowledged by Applicant, the size of each implant corresponds to its hinge radius and to its slide surface radius of curvature. In addition, this size or radius is determined based upon the tomograph. Thus, since size is determined by the tomograph, the radius of the joint or slide surface curvature is as well. In addition, Berry discloses selecting a prosthesis with a hinge radius approximating the hinge radius of the affected joint, i.e. the implant is sized to accommodate individual anatomy: "The invention is sized to provide as little disruption to the adjacent vertebrae for the cartilage which the joint is being replaced as is possible." *Id.* and column 9, lines 39-42.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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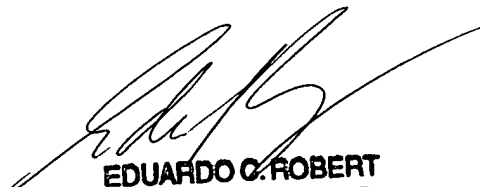
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock
07 March 2005



EDUARDO C. ROBERT
PRIMARY EXAMINER